Talvey (talquetamab-tgvs)
PAM – 079

Iowa Medicaid Program	Prior Authorization	**Effective Date**	01/01/2024
Revision Number	3	**Last Reviewed**	07/17/2026
Reviewed By	Medicaid Medical Director	**Next Review**	07/16/2027
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	07/19/2024

Overview

Medication: [1]	talquetamab-tgvs
Brand Name:	Talvey™
Pharmacologic Category:	Antineoplastic; bispecific GPRC5D-directed CD3 T-cell engager
FDA-Approved Indication(s):	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. ➢ Accelerated Approval: This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
How Supplied:	Single-dose vial containing either 3 mg/1.5 mL (2 mg/mL) or 40 mg/mL

Dosage and Administration: Talvey™ may be dosed weekly or biweekly (every 2 weeks); each regimen has a step-up dosing schedule.

WEEKLY Dosing Schedule			
SCHEDULE	**Day**	**Dose**	
Step-up dosing schedule	Day 1	Step-up dose 1 *	0.01 mg/kg
	Day 4	Step-up dose 2 *	0.06 mg/kg
	Day 7	First treatment dose	0.4 mg/kg
Weekly dosing schedule	One week after first treatment dose and weekly thereafter	Subsequent treatment doses	0.4 mg/kg once weekly

BIWEEKLY (Every 2 Weeks) Dosing Schedule			
SCHEDULE	**Day**	**Dose**	
Step-up dosing schedule	Day 1	Step-up dose 1 *	0.01 mg/kg
	Day 4	Step-up dose 2 *	0.06 mg/kg
	Day 7	Step-up dose 3 *	0.4 mg/kg
	Day 10	First treatment dose	0.8 mg/kg
Biweekly (every 2 weeks) dosing schedule	Two weeks after first treatment dose and every 2 weeks thereafter	Subsequent treatment doses	0.8 mg/kg every 2 weeks

* Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of all doses within the step-up dosing schedule. See boxed warning.

Benefit Category:	Medical

BOXED WARNING: CYTOKINE RELEASE SYNDROME (CRS) and NEUROLOGIC TOXICITY INCLUDING IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME (ICANS)
Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving Talvey™. Initiate treatment with step-up dosing to reduce the risk of CRS. Withhold Talvey™ until CRS resolves or permanently discontinue based on severity. **Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)** and serious and life-threatening reactions, can occur with Talvey™. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment and treat promptly. Withhold or permanently discontinue Talvey™ based on severity. **Tecvayli® and Talvey™ REMS:** Because of the risk of CRS and neurologic toxicity, including ICANS, Talvey™ is available only through a restricted program called the TECVAYLI and TALVEY Risk Evaluation and Mitigation Strategy (REMS).

Descriptive Narrative

Multiple myeloma (MM) is a malignant hematological disorder characterized by the clonal proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures. Most patients with MM present with signs or symptoms related to the infiltration of plasma cells into the bone or other organs or to kidney damage from immunoglobulin deposition. While the clinical presentation is usually subacute, a small percentage of patients present acutely with findings that require rapid attention and intervention (e.g., spinal cord compression, kidney failure, hyperviscosity).

The acronym "CRAB" is sometimes used to remember myeloma-defining events that are used in the diagnosis of MM: **c**alcium elevation; **r**enal insufficiency (kidney impairment); **a**nemia; and **b**one disease. It is important to distinguish MM both from other causes of the clinical presentations above and from other plasma cell dyscrasias for the purposes of prognosis and treatment.

MM primarily affects older individuals, the median age at diagnosis is 65 to 74 years. It is slightly more frequent in men than in women (approximately 1.4:1), and while MM occurs in all races and all geographic locations, the incidence varies by ethnicity. The incidence in African Americans and Black populations is two to three times that in White populations in studies from the United States and United Kingdom. In contrast, the risk is lower in the Japanese and Mexican populations.[2]

Data from the US Surveillance, Epidemiology, and End Results (SEER) registry estimates 36,000 new cases of MM and 10,850 deaths from MM in the United States in 2026 (representing 1.7 percent of all new cancer cases and 1.7 percent of all cancer deaths). This correlates with an annual incidence of 7.4 per 100,000 men and women per year, and an annual death rate of 2.8 per 100,000 men and women per year.[3]

Treatment alleviates symptoms, reverses cytopenias, and decreases end-organ damage, and it aims to achieve a sustained response, improve quality of life, and prolong overall survival (OS). While most patients with multiple myeloma will have an initial response to treatment, conventional therapy is not curative, and MM will ultimately relapse. In addition, a minority will have primary refractory disease that does not respond to initial treatment.[4]

Guidelines

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. The guidelines are developed and updated by 63 individual panels, comprising over 1,900 clinicians and oncology researchers from the 33 NCCN Member Institutions. The categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel.

The library of NCCN Guidelines® currently apply to more than 97 percent of people living with cancer or anyone at risk for a diagnosis of cancer in the United States. The guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management and are intended to assist all individuals who impact decision-making in cancer care, including physicians, nurses, pharmacists, payers, patients and their families, and others.

The NCCN Guidelines® provide recommendations based on the best evidence available at the time they are derived. Because new data are published continuously, it is essential that the NCCN Guidelines also be continuously updated and revised* to reflect new data and clinical information that may add to or alter current clinical practice standards.[5,6]

The information referenced at the time of this policy writing/revision (note version number and effective date) is from the NCCN Guidelines® for:[7]

- Multiple Myeloma (v.5.2026 – January 9, 2026)

* To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

NCCN Guidelines® Recommendation(s)	PREVIOUSLY TREATED MULTIPLE MYELOMA [a, b] – Relapsed/Refractory Disease After 3 Prior Lines of Therapy
(1) Preferred [c] a. After at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteosome inhibitor (PI), and an immunomodulatory agent (IMiD) i. Bispecific Antibodies (BsAb): Talquetamab-tgvs: Category 2A [d] (2) Useful in Certain Circumstances [c] a. Talquetamab + Teclistamab: Category 2A [d]	

[a] Regimens included under 1–3 prior therapies can also be used later in the disease course. Attempt should be made to use drugs/drug classes the patients have not been exposed to or exposed to >1 line prior.
[b] Autologous HCT should be considered in eligible patients who have not previously received HCT or had a prolonged response to initial HCT.
[c] Patients can receive more than one B-cell maturation antigen (BCMA) targeted therapy. Optimal sequencing of sequential BCMA targeted therapies is not known; however accumulated data suggests immediate follow on with second BCMA directed therapy after relapse may be associated with lower response rates.
[d] Prophylactic tocilizumab may be considered prior to first dose to reduce the risk of CRS.

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale [8]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and to determine appropriate treatment and prognosis.

Grade	ECOG Performance Status [Synonyms: WHO/Zubrod score]
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.
5	Dead.

Criteria

Prior authorization is required.

Talvey™ is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of multiple myeloma; **AND**
2. Member has relapsed or refractory disease after four or more prior therapies, which include at least **ONE OF EACH** from the following categories:
    a. An anti-CD38 monoclonal antibody; **AND**
    b. An immunomodulatory agent; **AND**
    c. A proteasome inhibitor; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2; **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Member will receive Talvey™ at a facility that is certified under the TECVAYLI and TALVEY Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
7. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 0.4 mg/kg once weekly OR 0.8 mg/kg every 2 weeks (after initial step-up dosing schedule); or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Talvey™ is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist; **AND**
4. Member will receive Talvey™ at a facility that is certified under the TECVAYLI and TALVEY Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
5. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 0.4 mg/kg once weekly OR 0.8 mg/kg every 2 weeks; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	0.4 mg/kg once weekly OR 0.8 mg/kg every 2 weeks (after completion of step-up dosing schedule)	0.4 mg/kg once weekly OR 0.8 mg/kg every 2 weeks

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
~~C9163~~	~~Injection, talquetamab-tgvs, 0.25 mg~~ *(effective 01/01/2024 to 3/31/2024)*
J3055	Injection, talquetamab-tgvs, 0.25 mg *(effective 04/01/2024)*

ICD-10	Description
C90.0	Multiple myeloma
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
57894-0469-01 (3 mg/1.5 mL)	Janssen Biotech, Inc. (57894)	0.25 mg	1	EA	12
57894-0470-01 (40 mg/mL)	Janssen Biotech, Inc. (57894)	0.25 mg	1	EA	160

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current

literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Talvey™ prescribing information (10/2025). Janssen Biotech, Inc.: Horsham, PA. Available online: www.talveyhcp.com. Accessed May 21, 2026.

[2] Laubach JP. Multiple myeloma: Clinical features, laboratory manifestations, and diagnosis. Connor RF, ed., ed. UpToDate. Waltham, MA: UpToDate, Inc. www.uptodate.com. Accessed May 11, 2026.

[3] SEER Cancer Stat Facts: Myeloma. National Cancer Institute. Bethesda, MD. Available online at seer.cancer.gov/statfacts/html/mulmy.html. Accessed May 12, 2026.

[4] Laubach JP. Multiple myeloma: Overview of management. Connor RF, ed., ed. UpToDate. Waltham, MA: UpToDate, Inc. www.uptodate.com. Accessed May 12, 2026.

[5] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[6] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[7] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- Multiple Myeloma (v.5.2026 – January 9, 2026)

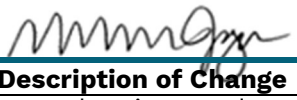
[8] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
07/17/2026	CAC	Annual review. Updated annual incidence statistics as provided by the American Cancer Society. NCCN Guidelines updated. Updated other references where applicable.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/18/2025	CAC	Annual review. Updated SEER data with 2025 information. Updated footnote in NCCN Guidelines and updated references.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/19/2024	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee